

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/820,848 Confirmation No. 8673  
Applicant : Lawrence V. Tannenbaum  
Filed : April 09, 2004  
  
TC/A.U. : 1631  
Examiner : LIN, Jerry  
  
Docket No. : CHPPM 03-22 03  
Customer No. : 27370  
  
For: METHOD FOR FIELD-BASED ECOLOGICAL RISK  
ASSESSMENT USING RODENT SPERM ANALYSIS

**DECLARATION UNDER 37 C.F.R. 1.132**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

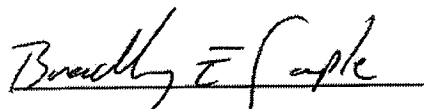
I, Dr. B. E. Sample, hereby declare and state that:

1. I am the primary author of Sample, B.E. et al., *Toxicological Benchmarks for Wildlife: 1996 Revision*. ES/ER/TM-86/R3 Oak Ridge National Laboratory, Oak Ridge, TN, USA.
2. This article is one of the more frequently cited and applied sources of toxicity data currently used in the field of ecological risk assessment.
3. Risk assessment for mammalian wildlife species at contaminated sites, such as U.S. EPA Superfund sites, relies extensively on comparisons of modeled contaminant exposure estimates to literature-derive toxicity reference values (TRVs). TRVs are typically derived from laboratory studies in which the toxicological responses of chemically-dosed test animals are measured. The test animals most frequently used in these studies are rats and mice.
4. Implicit in the application of TRVs derived from rodents is that toxicological effects that are elicited in rodents are analogous to those that may occur in other

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mammals. As a consequence, toxicity to rodents is used as a surrogate for effects to other mammals, such as shrews, voles, fox, or deer, that may be of greater value in the terrestrial ecological assessments. Nearly 85% of the mammalian toxicity studies I compiled for the above article had either mice or rats as the laboratory test species.

5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

  
Dr. B. E. Sample

31 March 2009  
Date